



PATENT #6

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In re the Application of

Shirley MIEKKA et al.

Serial No.: 09/960,703

: Group Art Unit: 1744

Filed: September 24, 2001

: Examiner: Not yet assigned

For: METHODS FOR STERILIZING
BIOLOGICAL MATERIALS
CONTAINING NON-AQUEOUS
SOLVENTS

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).

— 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).

— a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart

foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

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— c. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.

— 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).

— a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

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X 4. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
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Date: April 23, 2002

MLF:DRM:kpc

LIST OF PRIOR ART CITED BY APPLICANT (PTO-1449)		ATTY. DOCKET NO. CI-0012	APPLN. SERIAL NO. 09/960,703
		APPLICANT(S) Shirley MIEKKA et al.	
		FILING DATE September 24, 2001	GROUP 1744
		OTHER ART (including Author, Title, Date, Patent Pages, Publisher, Place of Publication, Etc.)	
	O. Cornu et al., Effect of Freeze-Drying and Gamma Irradiation on the Mechanical Properties of Human Cancellous Bone, 2000, pps. 426-431, Journal of Orthopaedic Research, Vol. 18		
	Anna Dziedzic-Goclawska et al., Effect of Radiation Sterilization on the Osteoinductive Properties and the Rate of Remodeling of Bone Implants Preserved by Lyophilization and Deep-Freezing, November 1991, pps. 30-37, Clinical Orthopaedics and Related Research, No. 272		
	Ole T. Jensen et al., Vertical Guided Bone-Graft Augmentation in a New Canine Mandibular Model, 1995, pps. 335-343, The International Journal of Oral and Maxillofacial Implants, Vol. 10, No. 3		
	Ronald W. Katz et al., Radiation-Sterilized Insoluble Collagenous Bone Matrix is a Functional Carrier of Osteogenin for Bone Induction, 1990, pps. 183-185, Calcified Tissue International, Vol. 47		
	Everard Munting et al., Effect of Sterilization on Osteoinduction; 1988, pps. 34-38, Acta Orthop Scand, Vol. 59, No. 1		
	P.A. Puolakkainen et al., The Effect of Sterilization on Transforming Growth Factor β Isolated From Demineralized Human Bone, 1993, pps. 679-685, Transfusion, Vol. 33, No. 8		
	U. Ripamonti et al., Long-Term Evaluation of Bone Formation by Osteogenic Protein 1 in the Baboon and Relative Efficacy of Bone-Derived Bone Morphogenetic Proteins Delivered by Irradiated Xenogeneic Collagenous Matrices, 2000, pps. 1798-1809, Journal of Bone and Mineral Research, Vol. 15, No. 9		
	A. Salehpour et al., Dose-Dependent Response of Gamma Irradiation on Mechanical Properties and Related Biochemical Composition of Goat Bone-Patellar Tendon-Bone Allografts, 1995, pps. 898-906, Journal of Orthopaedic Research, Vol. 13		
	Nikolaus Schwarz et al., Irradiation-sterilization of Rat Bone Matrix Gelatin, 1988, pps. 165-167, Acta Orthop Scand, Vol. 59, No. 2		
	C.W. Smith et al., Mechanical Properties of Tendons: Changes With Sterilization and Preservation, February 1996, pps. 56-61, Journal of Biomechanical Engineering, Vol. 118		
	Yukiyoshi Toritsuka et al., Effect of Freeze-Drying or γ -Irradiation on Remodeling of Tendon Allograft in a Rat Model, 1997, pps. 294-300, Journal of Orthopaedic Research, Vol. 15		
	Konrad Wangerin et al., Behavior of Differently Sterilized Allogenic Lyophilized Cartilage Implants in Dogs, 1987, pps. 236-242, J. Oral Maxillofac Surg, Vol. 45		
	S. Wientroub et al., Influence of Irradiation on the Osteoinductive Potential of Demineralized Bone Matrix, 1988, pps. 255-260, Calcified Tissue International, Vol. 42		
EXAMINER	DATE CONSIDERED		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.